

### **Remarks**

Prior to this amendment, claims 2-5, 25, 27-33, 35, 36, and 80-89 were pending in this application, of which claims 27-33, 35, 36, and 82-89 have been withdrawn from consideration. Claims 2-4 and 89 are amended herein. New claims 90-98 are added.

Claim 4 is amended to correct matters of form. Support for the amendment of claims 2, 3, and 89 can be found in the specification at page 35, line 25. Support for new claims 90, 91, 93, 94, and 97 can be found in the specification at page 27, lines 19-25. Support for new claims 92, 95 and 96 can be found in the specification at page 35, line 25. Support for new claim 98 can be found in the specification at page 67, lines 3-4.

Applicants believe that no new matter has been added by these amendments. Applicants reserve the right to pursue any removed subject matter in a related application. After entry of this amendment, **claims 2-5, 25, 27-33, 35, 36, and 80-98 are pending** (of which claims 27-33, 35, 36, and 80-89 continue to be withdrawn). Reconsideration of the pending claims is respectfully requested.

### ***Withdrawal of Rejections***

Applicants thank Examiner Archie for withdrawing the rejection of claim 5 under 35 U.S.C. §112, first paragraph (written description) and the rejection of claims 25 and 81 under 35 U.S.C. §112, first paragraph (enablement). Applicants also thank Examiner Archie for withdrawing the rejection of claims 5-6 and 77-79 under 35 U.S.C. §102(b).

### **Claim Rejections Maintained**

#### ***Claim Rejections Under 35 U.S.C. §112 (written description)***

Claims 2 and 25 continue to be rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner “interprets claim 2 as set forth . . . in a) as any amino acid sequence shown in SEQ ID NO: 11” (Office action at page 5). Applicants disagree.

However, solely to advance prosecution in this case, claim 2, part (a) is amended to recite “the amino acid sequence set forth as SEQ ID NO: 11”, as suggested by the Examiner on page 12 of the Office action.

The claims are further rejected because the specification allegedly “lacks written description of any fragment or variant that provides the requisite function of eliciting an immune response” (Office action at page 7). Applicants disagree. However, solely to advance prosecution in this case, claim 2, part (b) is amended to be directed to “an amino acid sequence at least 98% identical to the amino acid sequence set forth as SEQ ID NO: 11”. Applicants clearly contemplated and provided explicit written description of polypeptides comprising at least 98% sequence identity to SEQ ID NO: 11 (specification, for example, at page 22, lines 21-23; page 35, lines 24-27). As the specification provides guidance regarding conservative amino acid substitutions, the specification clearly identifies which residue substitutions can be accomplished without loss of immunogenicity. Moreover, an amino acid sequence having at least 98% sequence identity to SEQ ID NO: 11 has a maximum of only six amino acid substitutions. Such polypeptide variants would be readily identified by one of ordinary skill in the art.

In addition, Applicants clearly contemplated and provided explicit written description of immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11 (for example, at page 36, lines 5-7 and page 67, lines 3-4). As tools to identify immunogenic epitopes of known sequences were well known and readily available at the time the application was filed (for example, Singh and Raghava, *Bioinformatics*, 17(12):1236-1237, 2001), immunogenic fragments comprising “at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11” which elicit an immune response would easily have been identified by one of ordinary skill in the art.

In light of the above arguments and amendments, Applicants submit that claim 2 is sufficiently described by the specification and request that the rejection of this claim under 35 U.S.C. § 112, first paragraph, be withdrawn. Claim 25 depends from amended claim 2, and incorporates all the limitations thereof. In light of the above amendments, Applicants respectfully request that this rejection of claims 2 and 25 be withdrawn.

### *Claim Rejections Under 35 U.S.C. §102*

Claim 2 is rejected as allegedly anticipated under 35 U.S.C. §102(b) by Jacobs *et al.* (WO9920644; published April 29, 1999) because the Examiner “interprets claim 2 as set forth . . . in a) as any amino acid sequence shown in SEQ ID NO: 11” (Office action at page 8). Applicants respectfully disagree. However, as discussed above, claim 2 is amended to recite “the amino acid sequence set forth as SEQ ID NO: 11”. Jacobs *et al.* does not teach the amino acid sequence set forth as SEQ ID NO: 11 or an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11. In light of the above amendment, Applicants respectfully request that this rejection of claim 2 be withdrawn.

### **New Grounds for Objection**

#### *Claim Objection*

The claims are objected to because claim 89, added in the Amendment and Response filed on February 11, 2008, was missing from the claim set submitted with the Amendment and Response filed on September 29, 2008. Applicants thank Examiner Archie for pointing out this inadvertent omission and have replaced withdrawn claim 89 in the claim set submitted herewith. In view of the above amendment, Applicants respectfully request that this objection be withdrawn.

### **New Grounds for Rejection**

#### *Claim Rejections Under 35 U.S.C. §112 (written description)*

Claims 3-4 and 81 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner “interprets claim 3 as set forth . . . as any amino acid sequence shown in SEQ ID NO: 11” (Office action at page 10). Applicants disagree. However, solely to advance prosecution in this case, claims 3 and 4 are amended to recite “the

amino acid sequence set forth as SEQ ID NO: 11”, as suggested by the Examiner on page 12 of the Office action.

The claims are further rejected because the specification allegedly “lacks written description of any fragment or variant that provides the requisite function of eliciting an immune response” (Office action at page 12). Applicants disagree. However, solely to advance prosecution in this case, claim 3 is amended to be directed to “an amino acid sequence at least 98% identical to the amino acid sequence set forth as SEQ ID NO: 11”. Applicants clearly contemplated and provided explicit written description of polypeptides comprising at least 98% sequence identity to SEQ ID NO: 11 (specification, for example, at page 22, lines 21-23; page 35, lines 24-27). As the specification provides guidance regarding conservative amino acid substitutions, the specification clearly identifies which residue substitutions can be accomplished without loss of immunogenicity. Moreover, an amino acid sequence having at least 98% sequence identity to SEQ ID NO: 11 has a maximum of only six amino acid substitutions. Such polypeptide variants would be readily identified by one of ordinary skill in the art.

In addition, Applicants clearly contemplated and provided explicit written description of immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11 (for example, at page 36, lines 5-7 and page 67, lines 3-4). As tools to identify immunogenic epitopes of known sequences were well known and readily available at the time the application was filed (for example, Singh and Raghava, *Bioinformatics*, 17(12):1236-1237, 2001), immunogenic fragments comprising “at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11” which elicit an immune response would easily have been identified by one of ordinary skill in the art.

Claim 81 depends directly from amended claim 3 and incorporates all the limitations thereof. In light of the above amendments and discussion, Applicants respectfully request that this rejection of claims 3, 4, and 81 be withdrawn.

*Claim Rejections Under 35 U.S.C. §102*

Claims 3-4 are rejected as allegedly anticipated under 35 U.S.C. §102(b) by Jacobs *et al.* (WO9920644; published April 29, 1999) because Jacobs *et al.* teach “any amino acid sequence shown in SEQ ID NO: 11” (Office action at page 13). Applicants respectfully disagree. However, as discussed above, claims 3 and 4 are amended to recite “the amino acid sequence set forth as SEQ ID NO: 11”. Jacobs *et al.* does not teach the amino acid sequence set forth as SEQ ID NO: 11 or an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11. In light of the above amendments, Applicants respectfully request that this rejection of claims 3-4 be withdrawn.

*Request for Rejoinder*

In accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600 and as requested in the Amendment and Response to Restriction Requirement submitted on August 15, 2007, Applicants respectfully request that method claims which depend from or otherwise include all the limitations of any allowed composition claims be rejoined and examined.

**Conclusion**

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

Respectfully submitted,

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